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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,574	01/26/2007	Nicholas S. Arini	PA0363	5871

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GE HEALTHCARE BIO-SCIENCES CORP.  
PATENT DEPARTMENT  
101 CARNEGIE CENTER  
PRINCETON, NJ 08540

EXAMINER
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BITAR, NANCY

ART UNIT	PAPER NUMBER
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2624

NOTIFICATION DATE	DELIVERY MODE
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06/28/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

melissa.leck@ge.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/561,574	<b>Applicant(s)</b> ARINI ET AL.	
	<b>Examiner</b> NANCY BITAR	<b>Art Unit</b> 2624	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 20-35 is/are rejected.
- 7) ☒ Claim(s) 16-19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/19/2005, 11/16/2009, 04/15/2010</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation " first time " and second time" is unclear whether the terms are used as first image at time t and second image at t=1. it is unclear what applicant means whether the marker identifies same object or different object at different times. Furthermore, the meaning of "less capable of identifying" is unclear insofar as it leaves the reader in doubt whether known methods of the prior art fall under the scope of the claim, or not. E.g. all fluorescent markers, which are commonly used in the field, fall under the definition of claim 1, since a fluorescent marker is only capable to identify e.g. a cell nucleus when irradiated with an appropriate wavelength. When the irradiation source is switched off, the dye naturally is less capable of providing this function. Appropriate correction is required.

**Examiner Notes**

Examiner cites particular columns and line numbers in the references as applied to the claims below for the convenience of the applicant. Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply as well. It is respectfully requested that, in preparing responses, the applicant fully consider the references in entirety as potentially teaching all or part

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of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the examiner.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The USPTO "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (Official Gazette notice of 22 November 2005), Annex IV, reads as follows:

Descriptive material can be characterized as either "functional descriptive material" or "nonfunctional descriptive material." In this context, "functional descriptive material" consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of "data structure" is "a physical or logical relationship among data elements, designed to support specific data manipulation functions." The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993).) "Nonfunctional descriptive material" includes but is not limited to music, literary works and a compilation or mere arrangement of data.

When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized. Compare *In re Lowry*, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994) (claim to data structure stored on a computer readable medium that increases computer efficiency held statutory) and *Warmerdam*, 33 F.3d at 1360-61, 31 USPQ2d at 1759 (claim to computer having a specific data structure stored in memory held statutory product-by-process claim) with *Warmerdam*, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure per se held nonstatutory).

In contrast, a claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program's functionality to be realized, and is thus statutory. See *Lowry*, 32 F.3d at 1583-84, 32 USPQ2d at 1035.

Claim(s) 34-35 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter as follows. Claim 34 and 35 defines “ a computer software “ and “a data carrier” embodying functional descriptive material. However, the claim does not define a computer-readable medium or memory and is thus non-statutory for that reason (i.e., “When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized” – Guidelines Annex IV). That is, the scope of the presently claimed “ a computer software “ and “a data carrier” can range from paper on which the program is written, to a program simply contemplated and memorized by a person. The examiner suggests amending the claim to embody the program on “non-transitory computer-readable medium” or equivalent in order to make the claim statutory. Any amendment to the claim should be commensurate with its corresponding disclosure.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barker et al ( US 5,347,139) in view of Davidson et al ( US 4,389,670) and further in view of

As to claims 1-3, Barker et al teaches the method of analyzing a plurality of biological entities using an imaging apparatus, the method comprising:

a) providing a marker for said plurality of biological entities, said marker being capable of identifying objects within said plurality of biological entities when detected using the imaging apparatus, wherein said marker is capable of identifying said objects during a first time period, and said marker is less capable of identifying said objects during a second time period (The first exposure, image 1, is of the sample directly on the phosphor screen. The second exposure, image 2, is made with the appropriate absorption material between the sample and screen. Both images are captured. By using simultaneous equations isotope contributions of each label can be determined, see abstract; see also claim 10); b) during the first time period, recording a marked-up image in which spatial definitions of said objects are identifiable from said marker; c) during the second time period, recording a first image of said plurality of biological entities( ; and

While Barker meets a number of the limitations of the claimed invention, as pointed out more fully above, Barker fails to specifically teach said marker is less capable of identifying said object during a second time period. Davidson et al teaches the original image is converted into an array of numbers, each number being assigned to a given point in the image. The digital memory thus provides for the necessary quantification of the activity by the stored digital signal value as well as its accurate spatial location. Data manipulation such as background subtraction, intercomparisons (as in metabolic and catabolic rate studies), and radioactivity uptake, calculations and so forth, may be performed using digital computer means, column 5, lines 6-35) it would have been obvious to one of ordinary skill in the art to use the scanning control of Davidson in Barker et al in order to provide an electronic based method for improved two-dimensional detection of macromolecules distributed on a matrix which eliminates the time consuming photographic film exposure techniques ( column 2, lines 50-60 and column 5 lines 6-35). Neither Barker nor Davidson teaches “generating a spatial definition for an object in said first image using data derived from said marked-up image” . Hal et al teaches removing background and noise from images to generate dynamic spatial information of labelled objects, relying on the comparison and subtraction of sequentially recorded images [ (column 4, lines 33-48); ( column 18 lines 18-44, and lines 25-51) ] it would have been obvious to one skilled in the art to generate spatial definition by using the data derived from the second marked image as taught by Hal et al in order to minimize the time/labor effort invested for generating a spatial definition of the biologic entitle.. Therefore, the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention by applicant.

As to claim 4, barker et al teaches the method of claim 3, comprising adding said marker to said plurality of biological entities after recording of the first image ( claim 1).

As to claims 5-6, Davidson et al teaches the method of claim 1, wherein said marker has a temporally-varying signal ( column 2 lines 50-column 3 lines 1-35) .

The limitation of claims 7 and 8 has been defined by Davidson et al (column 4 , lines 22-55. )

As to claim 9, Barker et al teaches the method of claim 1, further comprising: e) during the first time period, recording a further image of said plurality of biological entities; and f) deriving data from said further image, and in step d), analyzing said first image using the data derived from the further image ( column 2 lines 3-30).

As to claims 10-11 , Hal et al teaches the method of claim 9, wherein said further image is recorded in a first color channel and said marked-up image is recorded in a second, different color channel ( column 19, lines 30-51).

As to claim 12, Hal et al teaches the method of claim 9, further comprising, in step f), deriving data from said further image using data derived from said marked-up image ( comparing two data images, column 18 lines 14-44).

As to claim 13, Hal et al teaches the method of claim 9, wherein the data derived in step f) comprises a value or values of one or more characteristics associated with the object ( claim 17) .

As to claim 14-15, Hal et al teaches the method of claim 13, wherein the one or more characteristics include at least one selected from the group consisting of a mean intensity, a standard deviation, a variance, a kurtosis, an auto-correlation function, a spatial correlation

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measure, a textual correlation measure, an auto correlation function, a fractal dimension, an area, a perimeter, a length of a principle axis, a width of a principle axis, a compactness and an orientation ( claim 16).

As to claim 20, Hal et al teaches the method of claim 1, further comprising repeating step d) to generate a plurality of spatial definitions for a plurality of objects in said first image ( column 18 lines 25-51) .

As to claim 21, Barter et al teaches the method of claim 20, wherein the plurality of generated spatial definitions is filtered according to a quality criterion (column 2 lines 4-30).

The limitation of claims 22-35 has been addressed above.

### ***Claim Objections***

5. Claims 16-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### **Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY BITAR whose telephone number is (571)270-1041. The examiner can normally be reached on Mon-Fri (7:30a.m. to 5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vikram Bali can be reached on 571-272-7415. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nancy Bitar/  
Examiner, Art Unit 2624

/Wes Tucker/  
Primary Examiner, Art Unit 2624